C3 cont'd

amount of a mixture to a cosmetically or pharmaceutically acceptable vehicle wherein said mixture comprises cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent by weight of the composition, and from about 0.1 to 10.0 percent by weight of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof, and applying said mixture to the skin.

C4

19. A method of treating or reducing damage to the skin, wherein the damage is associated with a reduction or loss of skin barrier function, which comprises adding an effective amount of a mixture to a cosmetically or pharmaceutically acceptable vehicle wherein said mixture comprises cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent, and about 0.1 to about 10.0 percent of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof by weight of the composition, and applying said mixture to the skin.

REMARKS

The Examiner maintained the rejection of claim 19 under section 112, first paragraph for failing to describe subject matter such that one of ordinary skill in the art would be enabled to make and/or use the present invention. Specifically, the Examiner asserts that the specification lacks enablement for "preventing" damage to the skin. The Examiner's position is based on the reasoning that damage to the skin cannot be adequately predicted such that it is not possible to determine if damage has been prevented. In addition, in response to the submission of other patents using the term "preventing", the Examiner points out that each application is examined on its own merits. While Applicants maintain their position as provided in previous responses, Applicants amend claim 19 according to the Examiner's suggestion. Thus, Applicants respectfully request that the Examiner's rejections based on lack of enablement under 35 U.S.C. §112, first paragraph be withdrawn.

The Examiner maintains in the Final Office Action and comments on the rejection in the Advisory Action that Ribier et al. (U.S. Patent No. 5,650,166; "the '166 reference") in view of Subbiah (U.S. Patent No. 6,150,381; "the '381 reference") renders claims 1 to 20 of the present invention obvious under 35 U.S.C. §103(a) because a mixture includes ordered compositions like the lipid vesicles taught in the '166 reference. However, there is no support provided to indicate why or how one of ordinary skill in the art would understand that a mixture of the present invention is taught or suggested by a lipid vesicle described in the '166 reference. There is no teaching, suggestion or motivation in the art or the knowledge of one of ordinary skill in the art to support the assertion that mixing components is equivalent to or includes encapsulating components. As previously mentioned by Applicants, lipid vesicles are a discrete arrangement of its components. However, assuming *arguendo*, that one of ordinary skill in the art could find a that a

lipid vesicle is a subset of a mixture, the disclosure of this subset of a mixture is not a disclosure of the other subset of a randomly oriented combination. Thus, Applicants assert that the other subset of the term "mixture," namely the random solution of components achieved by addition of the components to a pharmaceutical or cosmetic vehicle is not taught or suggested by the '166 reference. As the Examiner has admitted and described the term "mixture" in the Advisory Action as being a broad term including as a subset, lipid vesicles, it is logical to conclude that the term "mixture" also includes a random solution of components, and is generally disclosed in the present invention.

The claims of the present invention are amended such that the mixture of cholesterol sulfate and exfoliant, N-acetyl glucosamine are added to a pharmaceutical or cosmetically acceptable vehicle. Support for this amendment is found in the present specification at page 5, lines 12 to 25, and no new matter is added. Specifically, in this section of the present specification, it is disclosed that the mixture of cholesterol sulfate and amino sugar are added to the vehicle of both therapeutic products and color cosmetic products, alike. This is not taught or suggested by the '166 reference which only discloses the use of these ingredients to form lipid vesicles. As taught at column 3, lines 57 to 67, the lipid membrane of the '166 vesicles can contain, *inter alia*, the cholesterol sulfate, and as taught at column 5, lines 59 to 67, the deep down acting active agent encapsulated inside of the vesicle can be N-acetylglucosamine. But, these two ingredients are not mixed. Their only relationship is that N-acetylglucosaime can be an active agent contained inside of the lipid vesicle formed by among other ingredients, cholesterol sulfate. There is no mixing of these ingredients, and the vesicles, not the ingredients themselves, are contained in a medium as taught at column 8, lines 32 to 35. This is especially true for N-acetylglucosamine as the '166 reference fails to teach or suggest adding the N-acetylglucosamine directly to a vehicle because it teaches that the N-acetylglucosamine is encapsulated within the lipid vesicle. Thus, since the '166 reference fails to teach an amino sugar added directly to the vehicle, there is no teaching or suggestion of the mixture of cholesterol sulfate and an amino sugar added to the vehicle by the '166 reference. This demonstrates, therefore, that the '166 reference, alone or in combination with the '381 reference, fails to render the present claims, as amended, obvious.

Finally, even if, a *prima facie* case could be made, it would be rebutted by the surprising results of the present invention. As noted in the present specification at page 4, lines 1 to 12, it is unexpected to find that two opposing components would not cancel each other out when combined and added as a mixture to a composition. The Examiner notes in the Advisory Action that the composition in Example 1 contains 29 ingredients, and its activity on the skin is compared to skin that is untreated. From this the Examiner finds that meaningful conclusions about the combined activity of 2 out of 29 ingredients in the comparison cannot be made. The fact that there are 27 additional ingredients is not of primary importance in comparison to what those other 27 ingredients are. Most of those additional ingredients, about two-thirds, are those

commonly found in a pharmaceutical or cosmetic vehicle, e.g., surfactant, propylene glycol, squalane, BHT, butylene glycol, water, carbowax PEG 3350, dimethicone copolyol, glycereth-26, glucam-E20, methylparaben, trisodium EDTA, allantoin, keltrol, carbopol 981, triethanolamine, phenoxyethanol, benzyl alcohol, and pigments, some of which are described at page 7, lines 16 to 30. The remaining 8 ingredients are sclareolide, white birch, chamomile, bisabolol, wheat bran extract, olive extract, and linoleic acid and they represent examples of the naturally occurring skin barrier component described in the present invention as the preferred embodiment at page 5, line 26 to page 7, line 15. However, the present invention begins with the finding that two ingredients, the cholesterol sulfate and the amino sugar, although they have opposing activities, when added as a mixture to a pharmaceutical or cosmetic vehicle, do not neutralize one another's activities, but rather their activity occurs in tandem, and can improve or maintain a healthy skin barrier. This is a surprising and unexpected finding that is not taught or suggested by the cited references, alone or combined.

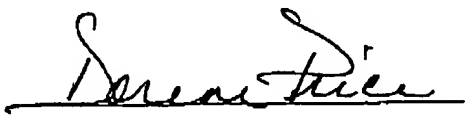
Because none of the cited references alone nor in combination would lead one of ordinary skill in the art to the compositions and methods of the present invention, a *prima facie* case of obviousness has not been established. Applicants request therefore, that the Examiner's rejection under §103 be withdrawn.

CONCLUSION

In view of the arguments presented above in the present submission, the claims are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

Date 10/01/02



Dorene M. Price (Reg. No. 43,018)
Estee Lauder Companies
125 Pinelawn Road
Melville, NY 11747
(631) 531-1194

MARKED AMENDMENTS

Please amend the claims as follows in their marked form.

1. A composition for topical application to the skin comprising a mixture of effective amounts of cholesterol sulfate or salts thereof, and an exfoliant added to a cosmetically or pharmaceutically acceptable vehicle.

13. A cosmetic or pharmaceutical formulation for topical application of a composition to the skin, the formulation containing a mixture comprising cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent, and from about 0.1 to about 10.0 percent by weight of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof by weight of the composition added to a cosmetically or pharmaceutically acceptable vehicle.

16. A method for improving or maintaining a healthy skin barrier which comprises[applying to the skin] adding an effective amount of a mixture to a cosmetically or pharmaceutically acceptable vehicle wherein said mixture [comprising] comprises cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent by weight of the composition, and from about 0.1 to 10.0 percent by weight of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof, and applying said mixture to the skin.

19. A method of treating or [preventing] reducing damage to the skin, wherein the damage is associated with a reduction or loss of skin barrier function, which comprises [applying to the skin] adding an effective amount of a mixture to a cosmetically or pharmaceutically acceptable vehicle wherein said mixture [comprising] comprises cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent, and about 0.1 to about 10.0 percent of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof by weight of the composition, and applying said mixture to the skin.